IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

SHAUNA EVELYN McMURRAY, individually and as a Natural Parent of I.K.M. and M.A.M., Minor Children	:	
Plaintiffs,	:	
vs.	:	**Case No.: 08-CV-381-GKF-TLW**
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE	:	
Defendant.	:	

DEFENDANT SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE'S MOTION TO COMPEL GENETIC TESTING PURSUANT TO F.R.C.P. 35 COMBINED WITH MEMORANDUM OF LAW IN SUPPORT OF MOTION

Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") files this Motion to Compel Plaintiff I.K.M. to submit to a blood draw and subsequent genetic testing under Federal Rule of Civil Procedure 35, respectfully showing the Court as follows:

I. INTRODUCTION

This is a product liability case in which Plaintiff Shauna McMurray alleges that her twin daughters, I.K.M. and M.A.M., suffer from congenital defects, including congenital cardiovascular malformations, that were caused by Ms. McMurray's ingestion of Paxil® ("Paxil"), a prescription medication manufactured and marketed by GSK, during her pregnancy. To obtain additional information about the congenital defects suffered by I.K.M., as well as to investigate potential alternative causes for these defects, counsel for GSK contacted Plaintiffs' counsel to schedule a medical examination of I.K.M. and M.A.M., which would include drawing blood to conduct genetic testing. Although Plaintiffs' counsel agreed to allow a physical

examination of I.K.M. and M.A.M., Plaintiffs' counsel advised that they would not allow genetic testing. (See E-mail Correspondence between Meredith A. Bunn, counsel for GSK, and Shawn P. Fox, counsel for Plaintiffs (attached as composite Exhibit A).) Accordingly, GSK is forced to seek this Court's assistance in requiring the genetic testing. See Herrerra v. Lufkin Indus., Inc., 474 F.3d 675, 689 (10th Cir. 2007) ("Notwithstanding Rule 35's requirements, however, physical and mental examinations are usually arranged by stipulation of the attorneys, ***with the rule standing as a compulsory sanction that helps to produce stipulations***.") (emphasis added; internal punctuation and citation omitted).

Pursuant to Federal Rule of Civil Procedure 35(a), GSK respectfully requests that this Court order Plaintiffs to submit I.K.M. to a blood draw in furtherance of genetic testing, by August 1, 2009. Genetic testing is warranted because the physical condition of I.K.M. is "in controversy." Medical examinations (including genetic testing) in personal injury cases like this one, when the plaintiff alleges that a defendant's product caused a physical injury, are permissible because the heart of such cases – the very controversies – are the plaintiff's physical conditions. Here, genetic testing is necessary for GSK to obtain information about I.K.M. so that GSK may be fully prepared to defend against Plaintiffs' claims and efforts to seek damages from GSK.

II. ARGUMENT & CITATION OF AUTHORITY

Federal Rule of Civil Procedure 35(a) authorizes a medical examination of a plaintiff when: (1) the party's physical or mental condition is "in controversy"; (2) good cause is shown; and (3) the examiner is "suitably licensed or certified". Fed. Civ. P. 35(a); Herrera v. Lufkin Indus., Inc., 474 F.3d 675, 688-89 (10th Cir. 2007); Lane v. Pfizer, Inc., No. 04-CV-683-CVE-PJC, 2007 WL 221959, *1 (N.D. Okla. Jan. 25, 2007). Rules of discovery, including Rule

35(a), are generally construed liberally in favor of granting discovery. See Schlagenhauf v. Holder, 379 U.S. 104, 115 (1964) (noting that a discussion of Rule 35 begins with the basic premise that discovery rules are "to be accorded a broad and liberal treatment").

This Court should grant GSK's Motion to Compel a Medical Examination in the form of genetic testing because Plaintiffs have placed I.K.M.'s physical condition in controversy and good cause exists for such testing.[1]

A. Plaintiffs Placed the Physical Condition of I.K.M. "In Controversy".

There is no question that Plaintiffs have placed I.K.M.'s physical condition in controversy in this litigation. Indeed, it is Plaintiffs' ***entire*** case. Plaintiffs allege that I.K.M. suffers from congenital defects as a result of Ms. McMurray's alleged use of Paxil during her pregnancy. Birth defects -- such as those suffered by I.K.M. -- have many causes, including genetic causes. Whether Paxil caused I.K.M.'s congenital defects or whether there are alternative causes for these defects are the ***core issues*** for the jury to decide at trial. Accordingly, GSK is entitled to conduct genetic testing to evaluate whether the conditions suffered by I.K.M. may be the result of a genetic cause. As the United States Supreme Court has recognized, "[a] plaintiff in a negligence action who asserts mental or physical injury … places that mental or physical injury clearly in controversy and provides the defendant with good cause for an examination to determine the existence and extent of such asserted injury." See Schlagenhauf, 379 U.S. at 119. This case is no exception -- Plaintiffs have clearly placed the physical condition of I.K.M. "in controversy".

[1] The blood may be drawn by any licensed physician or facility of Plaintiffs' choosing. GSK requests only that the resulting blood samples be forwarded to the genetic laboratories to be specified by GSK.

B. Good Cause Exists for Genetic Testing of I.K.M.

Plaintiffs allege that I.K.M. suffers from various physical symptoms and conditions that Plaintiffs attribute to Ms. McMurray's ingestion of Paxil during pregnancy. GSK anticipates that Plaintiffs will submit expert reports from physicians who, after examining I.K.M., will conclude that Paxil is responsible for her injuries. At trial, the jury will be asked to determine whether Paxil caused the congenital defects, including cardiovascular defects, suffered by I.K.M. or whether there were alternative causes. The genetic testing sought by GSK will provide GSK's experts the chance to investigate alternative causes of I.K.M.'s defects, specifically genetic causes, and formulate an opinion concerning the validity of Plaintiffs' claims. This examination will undoubtedly help the trier of fact in making its determination about whether Paxil caused I.K.M.'s congenital defects.

Congenital cardiovascular malformations occur in approximately 1% to 5% of all live births. (Affidavit of John W. Belmont, M.D. ("Belmont Aff."), at ¶ 4) (attached as Exhibit B). There are several lines of evidence supporting the genetic etiology (or cause) of congenital defects in general, and congenital cardiovascular malformations in particular. (Id.) A genetic etiology is even more compelling when the child's presentation is syndromic, *i.e.*, when the child's cardiac malformation is not isolated but is accompanied by defects in other organ systems and/or dysmorphic features. (Id.) The evidence in this case to date shows that I.K.M. was born with a congenital cardiovascular malformation known as coarcation of the aorta, accompanied by one or more ventricular septal defects, commonly known as a "hole in the heart." (Id. at ¶ 6.) In addition, I.K.M. had a cleft palate, a number of minor anomalies, and dysmorphic features[2].

[2] A dysmorphic feature is generally defined as a body characteristic that is abnormally formed.

(Id.) Based upon her clinical presentation, a genetic disorder or syndrome must be considered in the etiology of I.K.M.'s congenital defects. (Id.)

In developing its defense, GSK has a right to investigate the potential causes, including genetic causes, of the physical conditions suffered by I.K.M. GSK seeks only to conduct a single, minimally invasive blood draw from I.K.M. The blood samples would then be sent to particular laboratories to conduct the specific genetic testing sought by GSK's experts. (See Belmont Aff., at ¶ 8.) Plaintiffs have objected to producing I.K.M. for a blood draw because they claim that genetic testing has already been conducted. Plaintiffs are correct that *some* genetic testing has been conducted. Specifically, in 2006, Lab Corp. performed a karyotype, fluorescent in situ hybridization ("FISH") for 22q11 deletion, and a chromosomal microarray analysis. (Id. at ¶ 9.) For a number of reasons, the testing performed in 2006 should not be considered exhaustive of the genetic testing necessary to fully assess the potential causes of I.K.M.'s congenital defects.

Isolated or syndromic congenital cardiovascular malformations may be caused by chromosomal disorders, genomic disorders, or single gene mutations, many of which can be identified and confirmed through clinically validated testing. (Belmont Aff., at ¶ 5.) Due to technological advances and the rapid pace of genetic discovery, the ability to identify and detect genetic causes of cardiovascular malformations has improved dramatically, even since 2006 when Lab Corp. performed genetic testing of I.K.M. (See id.) In this regard, the testing conducted at the Lab Corp. facility in no way represents the full extent of genetic testing available. (See id. at ¶ 8 ("Not all genetics laboratories have the capability to perform every type of genetic test; various laboratories offer only a relative handful of clinically available assays to detect specific gene mutations, and fewer still offer appropriate high resolution

chromosomal microarray analysis."). Nor did the Lab Corp. analysis include testing designed to detect specific single gene mutations known to be associated with syndromes that are consistent with I.K.M.'s clinical presentation. (Id. at ¶¶ 7, 9.)

The mere fact that some genetic testing has been conducted is not sufficient to prohibit GSK from having *different* genetic testing performed. Magistrate Judge Cleary's decision in Lane v. Pfizer, Inc. is instructive on this point. In Lane, the plaintiff alleged that he suffered emotional distress and mental suffering as a result of the defendant's alleged discriminatory conduct. 2007 WL 221959 at *1. Accordingly, the defendant sought a medical examination to test the plaintiff's allegations. Similar to this case, the plaintiff objected to the examination because the defendant had previously examined the plaintiff as part of determining disability benefits. Id. This court held that the existence of the first examination did not preclude a subsequent examination for two reasons: (1) the first examination was conducted before any lawsuit was filed; and (2) the purpose of the first medical examination was distinct from that sought by the defendant in the lawsuit, i.e., to determine disability benefits versus to assess the cause of the plaintiff's mental illness. Id.

Likewise, in Doe v. District of Columbia, the District Court for the District of Columbia granted the defendant's motion to compel a medical examination of the plaintiff, despite the fact that the defendant had examined the plaintiff on multiple prior occasions. Doe, 229 F.R.D. 24, 27 (D.D.C. 2005). Distinguishing cases relied upon by the plaintiff, the Doe court held that the defendant's request was not simply to repeat an examination that it had already conducted. Id. Instead, the defendant sought to have a new physician perform new tests regarding injuries or conditions that had not been the subject of previous examinations. Id. Accordingly, the court held that good cause existed for the defendant to examine the plaintiff, noting that the

"Defendant surely has a right to develop a complete record of the nature and extent of plaintiff's injuries that resulted from the incidents alleged in this litigation." Id.; see also O'Sullivan v. Rivera, 229 F.R.D. 184, (D.N.M. 2004) (holding that there was good cause for physical examination, although previous examinations had been conducted, because "[t]he Court should afford the Defendants and their expert an opportunity to determine for themselves to what extent, if any this accident aggravated [plaintiff's] pre-existing injuries and have the opportunity to rebut the reports of the plaintiff's expert.") (internal citation and punctuation omitted)).

This Court should similarly reject Plaintiffs' argument that GSK should be prohibited from conducting additional genetic testing of I.K.M. I.K.M.'s treating physician performed the initial genetic testing in the ordinary course of treatment in 2006, well *before* Plaintiffs' filed this lawsuit. Even in Lane and Doe, where the defendants themselves conducted the previous pre-suit examinations, the courts declined to give the earlier examinations preclusive effect. Here, GSK had no involvement or input in the earlier, pre-suit genetic testing. Furthermore, and more importantly, GSK does not want to repeat testing already done. (Belmont Aff., at ¶9.) Not all genetic testing is created equally. GSK seeks to conduct genetic testing (different from that previously done by I.K.M.'s treater) to investigate potential genetic causes separate and distinct from those tested for during the earlier genetic testing. In particular, GSK would perform testing for single gene disorders (which have not been performed to date) as well as a chromosomal microarray analysis using a much higher resolution than that used by Lab Corp. in 2006. (This particular array has only recently become available for clinical use.) (Id.)

The additional genetic testing sought by GSK is medically warranted to shed light on the potential cause of I.K.M.'s congenital malformations. (Belmont Aff., at ¶ 10.) By attempting to prohibit GSK from conducting the genetic testing of its choosing, Plaintiffs are effectively

dictating the manner in which GSK can investigate and prepare its defense. Civil litigation should not and does not work that way. See Cutting v. United States, Civil Action No. 07-cv-02053-PAB-MEH, 2008 WL 5064267, *1 (D. Colo. Nov. 24, 2008) (finding good faith basis to allow defendant to draw blood from minor plaintiff and conduct genetic tests of its choosing and noting that "[t]he Court does not believe that artificially limiting Defendants on what tests may be run on the blood that is drawn will be the best use of resources."). Accordingly, GSK has established good cause for performing a single blood draw of I.K.M. in order to conduct non-duplicative genetic testing.

III. CONCLUSION

For all the reasons set forth above, GSK respectfully requests that this Court order Plaintiffs to submit I.K.M. to the genetic testing sought by GSK. Because of the short period of time between the filing of this motion and the deadline for GSK's expert disclosures and reports (September 14, 2009), GSK requests that this Court compel Plaintiffs to produce I.K.M. for the necessary blood draw by August 1, 2009. The timely completion of this testing is critical to GSK's experts' opinions and its expert should be allowed to conduct this examination before their opinions are disclosed.

Respectfully submitted, this 13th day of July, 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2009, a true and correct copy of the foregoing document was filed electronically and is available for viewing and downloading from the ECF system, and was served upon the following counsel via transmission of Notices of Electronic Filing generated by CM/ECF:

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